REMARKS/ARGUMENTS:

Applicants canceled claims 2, 9-11, 17, 18, and 29 without prejudice or disclaimer. Applicants reserve the right to reintroduce the subject matter of those claims at a later point in prosecution. Applicants amended claim 1. That amendment is supported in the specification, *e.g.*, in Example 5. Claims 1, 4-6, and 30-32 are currently pending in this application. Reconsideration and allowance of the application is respectfully requested.

Specification

The Office objected to the specification because "it contains an embedded hyperlink and/or other form of browser-executable code" and required deletion of the embedded hyperlink. Action at page 2. Applicants amended the specification to remove the embedded hyperlink. Applicants request reconsideration and withdrawal of the objection.

Rejection under 35 U.S.C. §112, first paragraph (written description) of claims 1, 2, 4-6, 9-11, 17, 18, and 30-32

The Office rejected claims 1, 2, 4-6, 9-11, 17, 18, and 30-32 under 35 U.S.C. §112, first paragraph, as allegedly lacking sufficient written description support. Action at page 3. The Office argued that Applicants' previous amendment "introduces new matter into the disclosure with the recitation of harvesting a population of neural cells, wherein at least 2% of the cells express tyrosine hydroxylase." Action at page 4 (emphasis in original). The Office contended that the specification "fails to provide specific description and support for this amendment." Id.

Applicants respectfully traverse these written description rejections. However, without acquiescing in the Office's rejection and solely to facilitate the prosecution of this application, Applicants have amended claim 1 to remove the 2% limitation added in the previous amendment. Claims 4-6 and 30-32 depend from claim 1 and so also now lack the added limitation. The amended claims now are directed to methods of producing a population of cells comprising tyrosine

hydroxylase-expressing neurons. Therefore, Applicants request reconsideration and withdrawal of the written description rejections.

The Office also stated that the above claims were further rejected on enablement grounds because a "disclosure cannot teach one to make or use something that has not been described." Action at page 5. Applicants point out that this is a misstatement of the law – the courts have long held that written description and enablement are separate doctrines and that a claim can lack written description support but still be enabled. *See, e.g., Fields v. Conover*, 443 F.2d 1386, 1391, 170 USPQ 276 (CCPA 1971) (stating "[o]ur finding that Conover's specification provides adequate how-to-make support for the counts does not end the case, for a specification may provide adequate teachings of how to make and use subject matter which is subsequently claimed and yet fail to contain a written description thereof which complies with the first requirement of the first paragraph of 35 USC 112."). Nevertheless, as discussed above, Applicants amended the claims to remove the added 2% limitation, so the issue is moot.

Rejection under 35 U.S.C. §112, first paragraph (enablement) of claims 1, 2, 4-6, 9-11, 17-18, and 30-32

The Office rejected claims 1, 2, 4-6, 9-11, 17-18, and 30-32 under 35 U.S.C. §112, first paragraph, as allegedly not being enabled by the specification. Action at page 5. The Office based its rejections on several grounds.

First, the Office argued that the claims are not enabled because they allegedly require feeder-free conditions, and that therefore "extracellular matrix must be provided." Action at page 6. Applicants traverse this basis for the rejections and disagree with the Office's contentions. The point of invention of the claimed methods is the use of a TGF-β Superfamily antagonist to generate tyrosine hydroxylase-expressing neurons from human embryonic stem cells. The growth/maintenance of the undifferentiated cells prior to differentiation is merely ancillary to this invention. Applicants have amended the claims to remove the feeder-free limitation as it is not necessary for the claimed

invention. Claims 4-6 and 30-32 all depend from claim 1. Thus, this basis for the Office's enablement rejections is now moot.

Second, the Office apparently contended that the specification is only enabling for the differentiation of hES cells to neurons. Action at page 7. Applicants disagree with this characterization. However, without acquiescing in the Office's rejection and solely to facilitate the prosecution of this application, Applicants have amended claim 1 so that they now are directed to the production of a population cells comprising tyrosine hydroxylase-expressing neurons. Thus, Applicants request reconsideration and withdrawal of this basis for its enablement rejections.

Third, the Office alleged that the "specification is only enabling for producing TH positive cells when utilizing noggin or follistatin." Action at page 8. The Office based this argument on its contention that Test Group 4 was "unable to provide any noticeable percentage of TH positive cells." Id.

Applicants respectfully traverse this basis for the enablement rejections. Applicants believe that the Office has misunderstood the claims and the data in Tables 3 and 4. The claims are directed to use of a TGF-β Superfamily antagonist. While Test Factor Group 5 contains the TGF-β Superfamily antagonists noggin and follistatin, Test Factor Group 4 contains TGF-β Superfamily agonists, which have the opposite effect of antagonists. For example, BDNF and NT-3 are not TGF-β Superfamily antagonists as stated by the Office in the Action at page 7. Thus, the results showing low neuronal production from Test Factor Group 4 factors in the absence of Test Factor Group 5 factors actually supports the claimed methods.

Fourth, the Office apparently based the enablement rejections in part on the issue of the percentage limitation added in the previous amendment (which added limitation is also subject to the new matter rejection above). Applicants respectfully traverse that basis for the rejections. However, without acquiescing in the Office's rejection and solely to facilitate the prosecution of this application,

Applicants have amended the claims to remove the added limitation. This basis for the enablement rejections is now moot.

For at least the above reasons, Applicants request reconsideration and withdrawal of the enablement rejections.

Fees Due

Should the Patent Office determine that a further extension of time or any other relief is required for further consideration of this application, Applicants hereby petition for such relief, and authorize the Commissioner to charge the cost of such petitions and other fees due in connection with the filing of these papers to Deposit Account No. 07-1139, referencing the docket number indicated above.

Respectfully submitted,

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